

REMARKS

Claims 1-20 are pending in the application.

Information Disclosure Statement

An Information Disclosure Statement on which is cited the titles of the cited references will be provided in due course.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1-20 have been rejected for allegedly not being enabled by the description. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

The Examiner has failed to establish *prima facie* non-enablement of the claimed invention. The Examiner's attention is directed to M.P.E.P. 2164.02, wherein it is stated as follows:

The issue of "correlation" is related to the issue of the presence or absence of working examples. "Correlation" as used herein refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use. An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention. If there is no correlation, then the examples do not constitute "working examples." In this regard, the issue of "correlation" is also dependent on the state of the prior art. In other words, if the art is such that a particular model is recognized as correlating to a specific

condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications).

Since the initial burden is on the examiner to give reasons for the lack of enablement, the examiner must also give reasons for a conclusion of lack of correlation for an *in vitro* or *in vivo* animal model example. A rigorous or an invariable exact correlation is not required, as stated in *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985).

Applicants note that the presently claimed invention directed to a method of reducing inflammation in kidney of a subject, comprising delivering to the kidney of the subject in need thereof a therapeutically effective amount of a gene encoding an anti-inflammatory or immunosuppressant protein, is fully enabled by the present specification.

In order to demonstrate the claimed invention, Applicants have used mammalian subjects, in particular, FGS/Kist mice, which develop nephritis, and the experimental evidence shows that the administration of certain cytokines into kidney cells in these animal models results in significantly reduced glomerulosclerosis.

In the face of this incontrovertible evidence of reduced glomerulosclerosis in art accepted animal model for nephritis in humans, the Examiner has failed to provide any evidence as to why

these results provided in the specification cannot correlate with treatment of nephritis in humans.

In the absence of such evidence, the presently claimed invention must be considered to be fully enabled by the specification. Removal of this rejection is respectfully requested.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

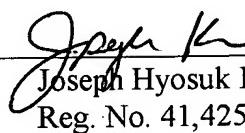
The Commissioner is authorized to charge JHK Law's Deposit Account No. **502486** for any fees required under 37 CFR §§ 1.16 and 1.17 that are not covered, in whole or in part, by a credit card payment enclosed herewith and to credit any overpayment to said Deposit Account No. **502486**.

Respectfully submitted,

JHK Law

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